



**Pre-application Webinar**  
**PAR-13-029 “Opportunities for Collaborative Research  
at the NIH Clinical Center”**

**Friday, January 11, 2013**  
**2:00 PM to 4:00 PM, EST**



# Webinar Agenda

- |   |                                |
|---|--------------------------------|
| I. Welcome & Overview of the Initiative                           | Dr. Collins                    |
| II. Resources, Opportunities & Working at the NIH Clinical Center | Dr. Gallin                     |
| III. Special Requirements for the FOA                             | Dr. Hayunga                    |
| IV. Scientific Peer Review for the FOA                            | Dr. Nakamura/<br>Dr. Schneider |
| V. Budget Preparation   | Ms. Joyce                      |
| VI. Tips for Preparing the Application                            | Dr. Ramsey-Ewing               |
| VII. Panel Discussion/Q&A   | Dr. Hayunga/Mr. Ellis          |

**Meeting URL:** <https://webmeeting.nih.gov/foapreappwebinar2013/>

**Call-in number:** 1-866-398-2885; **Passcode:** 247071

# **Panel Participants:**

## **NIH Intramural and Extramural Experts**

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- **Francis S. Collins, MD, PhD (OD)**
- **Valerie Bonham, JD (OGC)**
- **Bryan S. Clark, MBA (NICHD)**
- **Joseph Ellis (OER)**
- **John I. Gallin, MD (CC)**
- **Ann Hammersla, JD (OTT)**
- **Della Hann, PhD (OER)**
- **Eugene G. Hayunga, PhD (NICHD)**
- **Maria D. Joyce, CPA, MBA (CC)**
- **Richard Nakamura, PhD (CSR)**
- **Frederick P. Ognibene, MD (CC)**
- **Anna Ramsey-Ewing, PhD (NIAID)**
- **Sally J. Rockey, PhD (OER)**
- **Mark Rohrbaugh, JD, PhD (OTT)**
- **Donald Schneider, PhD (CSR)**
- **Constantine A. Stratakis, MD, DSc (NICHD)**

# Questions

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- We will remind you of how to pose questions frequently throughout the discussion.
- Please email any questions to:  
[ClinicalCtrPartner@mail.nih.gov](mailto:ClinicalCtrPartner@mail.nih.gov)
- We have individuals monitoring incoming questions in real-time.
- Questions received today will be addressed during the panel discussion at the end of this webinar.

# Welcome

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**Francis S. Collins, MD, PhD**

# **Resources, Opportunities & Working at the NIH Clinical Center**

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**John I. Gallin, M.D.  
Director, NIH Clinical Center**

# Mission

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**Science**



**Training**



**Patient Care/  
Safety**



# Clinical Center Profile

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- **240 beds**
- **More than 450,000 patients since opening in 1953**
- **Every patient on research protocol**
- **1,530 active protocols**
  - **Interventional/Clinical Trials - 723 (48%)**
  - **Natural History - 716 (47%)**
  - **Screening - 67 (4%)**
  - **Training - 24 (1%)**



# Major Emphasis

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- Study of the pathophysiology of disease
- First in human with new therapeutics
- Study of patients with rare diseases

**18 – 25 million people  
in the United States  
have a rare disease!**

# Rare Diseases at the NIH Clinical Center

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**The Clinical Center has the ability to assemble cohorts of patients with rare diseases**

- **Number of Rare Diseases      463**
- **Number of Protocols              692**

# Specialized Services and Facilities

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- **Phenotyping**
  - **Biomechanics laboratory**
  - **Metabolic chambers**



# Specialized Services and Facilities

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- Cell Processing/GMP Facility  
Transfusion Medicine Department



# Specialized Services and Facilities

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## Imaging Capabilities

- **MRI Center**
- **PET Program**
  - 3 cyclotrons
  - Radiochemistry/GMP Facility
  - 3 scanners





# 3T integrated simultaneous MRI-PET





# Specialized Services and Facilities

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## Pharmaceutical Development Service GMP Facility

- **Product formulation**
- **Analytical and quality control**
- **Pharmacokinetics**
- **Manufacturing capability (8 hour day)**
  - **75,000 capsules**
  - **150,000 tablets**
  - **220 liters**
  - **5,000 syringes**
  - **8,000 vials (includes vaccines and biologics)**



# New Website



Clinical Center Home >> Collaborating with NIH Intramural Investigators at the Clinical Center

## Collaborating with NIH Intramural Investigators at the Clinical Center

### More Information

>> [Welcome](#)

>> [About the NIH Clinical Center](#)

>> [Contact Us](#)

>> [Collaborations Home](#)

### Collaborations Home

This site is offered to illustrate the special resources at the NIH Clinical Center and to provide information on potential opportunities for collaboration.

#### Why external partnerships?

In December 2010, the Congressionally mandated [Scientific Management Review Board](#) recognized the potential benefits of opening the NIH Clinical Center to external investigators and [recommended doing so](#) (4 MB). Benefits include stimulating a broader range of research, especially translational research that bridges the bedside-to-bench gap.

Based on resource availability, collaborations include the [NIH Bedside-to-Bench Program](#), which fosters partnerships between NIH grantees and intramural clinical investigators and a new grant mechanism, "[Opportunities for Collaborative Research at the NIH Clinical Center \(U01\)](#)."

To support collaboration with external entities, the NIH Clinical Center has [catalogued assets](#) that may be of interest to external investigators. NIH is working diligently to make assets and opportunities for collaboration available to external investigators and to ensure that the proper infrastructure is in place for successful partnerships.



[Text version of the slideshow](#)

[Opportunities for Collaborative Research at the NIH Clinical Center \(U01\)](#)

### Collaborator's Toolkit

- >> [Resources](#)
- >> [Current Research](#)
- >> [Funding Opportunities](#)
  - >> [New U01](#)
- >> [How to Initiate a Collaboration](#)
- >> [Frequently Asked Questions](#)
- >> [Glossary](#)
- >> [Contact Us](#)

### Searches:

[CLINICAL STUDIES](#)

[INTRAMURAL ANNUAL RESEARCH REPORTS](#)



[Sign up to receive email updates for Opportunities for Collaboration with Intramural Investigators at the NIH Clinical Center](#)

<http://www.cc.nih.gov/translational-research-resources/>

# Working at the CC

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## Frequently Asked Questions

- Resources
- Collaborations
- NIH Appointments for Extramural Investigators
- Credentialing for Extramural Investigators
- Conflict of Interest
- Clinical Protocols
- Building a Budget for the U01 Funding Opportunity
- Patients
- Intellectual Property
- Biospecimens
- Workspace and Lodging for Extramural Partners
- Data

# **PAR-13-029 Highlights**

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**Eugene G. Hayunga, Ph.D.**  
**Director, Office of Extramural Policy**  
**NICHD**

# Purpose of the FOA

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- To support collaborative research projects aligned with NIH efforts to enhance the translation of basic biological discoveries into clinical applications that improve health
- To promote partnerships between NIH intramural and (non-NIH) extramural investigator
- To provide extramural investigators an opportunity to take advantage of the unique research resources of the NIH Clinical Center

# Overview

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- **12 participating ICs: NICHD, NCI, NEI, NHBLI, NHGRI, NIAAA, NIAID, NIAMS, NIBIB, NIDCD, NIDA, NLM; also ORWH and ODS**
- **Up to \$500K/year (direct costs) for up to 3 years**
- **U01 cooperative agreement mechanism**
- **Receipt dates: March 20, 2013 (also 2014 & 2015)**
- **Awards to be made early in FY (Nov/Dec)**



# Special Requirements

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- Teams **must** have one extramural and one intramural investigator (“Multiple PD/PI” strongly encouraged)
- Some of the work **must** be done at the NIH Clinical Center
- Budget **must** delineate extramural, intramural and Clinical Center costs
- Application **must** include letters of support from the Clinical Center and from the appropriate IC
- Application **must** include a collaboration plan and describe the advantages of the intramural/extramural partnership and the utilization of Clinical Center resources

# Letter of Intent

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- Not required, but strongly encouraged
- Submit 30 days before application due date
  - **No later than February 20, 2013**
- **Letter of Intent should include:**
  - Descriptive title of proposed research
  - Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
  - Names of other key personnel
  - Participating institution(s)
  - Number and title of this funding opportunity (PAR-13-029)
- **May also include:**
  - Brief research plan
  - Summary of the Clinical Center services planned for utilization
- **Letter of Intent can serve as your request for the Letters of collaboration/support from the Clinical Center and the relevant IC which are required**

# Required Letters of Support

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- **Letter from Clinical Center Director:**

- Clinical Center facilities will be able to accommodate the proposed research if the grant is awarded

- **Letter from Participating NIH Institute/Center:**

- research project is of programmatic relevance to that Institute/Center;
- Institute/Center has made a commitment to fund the Clinical Center and intramural investigator costs if an award is made; and
- intramural investigator at the Institute/Center will be allowed to devote time to the research project.

- **Letters of Support must be included when the application is submitted. *(Applications without both letters will be considered incomplete and will not be reviewed.)***

# Questions

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- Please email any questions to:  
[ClinicalCtrPartner@mail.nih.gov](mailto:ClinicalCtrPartner@mail.nih.gov)
- Questions received today will be addressed during the panel discussion at the end of this webinar

# **Scientific Peer Review**

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**Richard Nakamura, Ph.D.**  
**Director, Center for Scientific Review**

**Don Schneider, Ph.D.**  
**Senior Advisor to the CSR Director**

# Loci of Review

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IC Review	CSR Review
NCI	NEI
NIAAA	NIBIB
NIAID	NICHD
NIAMS	NIDA
NHGRI	NIDCD
NHLBI	NLM



# Peer Review Principles

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- **Conflicts will be excluded**
- **Most reviewers will be from outside the government (Federal employees cannot exceed 25% of members)**
- **Standard NIH procedures will be used by all review units, and every applicant will receive written feedback (a “summary statement”)**

# Criteria for Review

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## **The standard five**

- **Significance**
- **Investigators**
- **Innovation**
- **Approach**
- **Environment**

## **Protections as appropriate**

- **Human subjects**
- **Vertebrate animals**
- **Biohazards**

# **Additional Criteria for Review**

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- **Does Collaborative Plan define responsibilities for the intramural and the extramural investigators?**
- **Is a Management Plan presented, describing roles for each participant?**
- **Is an advantage of the collaborative partnership evident?**
- **Will unique research opportunities in the NIH Clinical Center be utilized?**

# Questions

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- Please email any questions to:  
[ClinicalCtrPartner@mail.nih.gov](mailto:ClinicalCtrPartner@mail.nih.gov)
- Questions received today will be addressed during the panel discussion at the end of this webinar

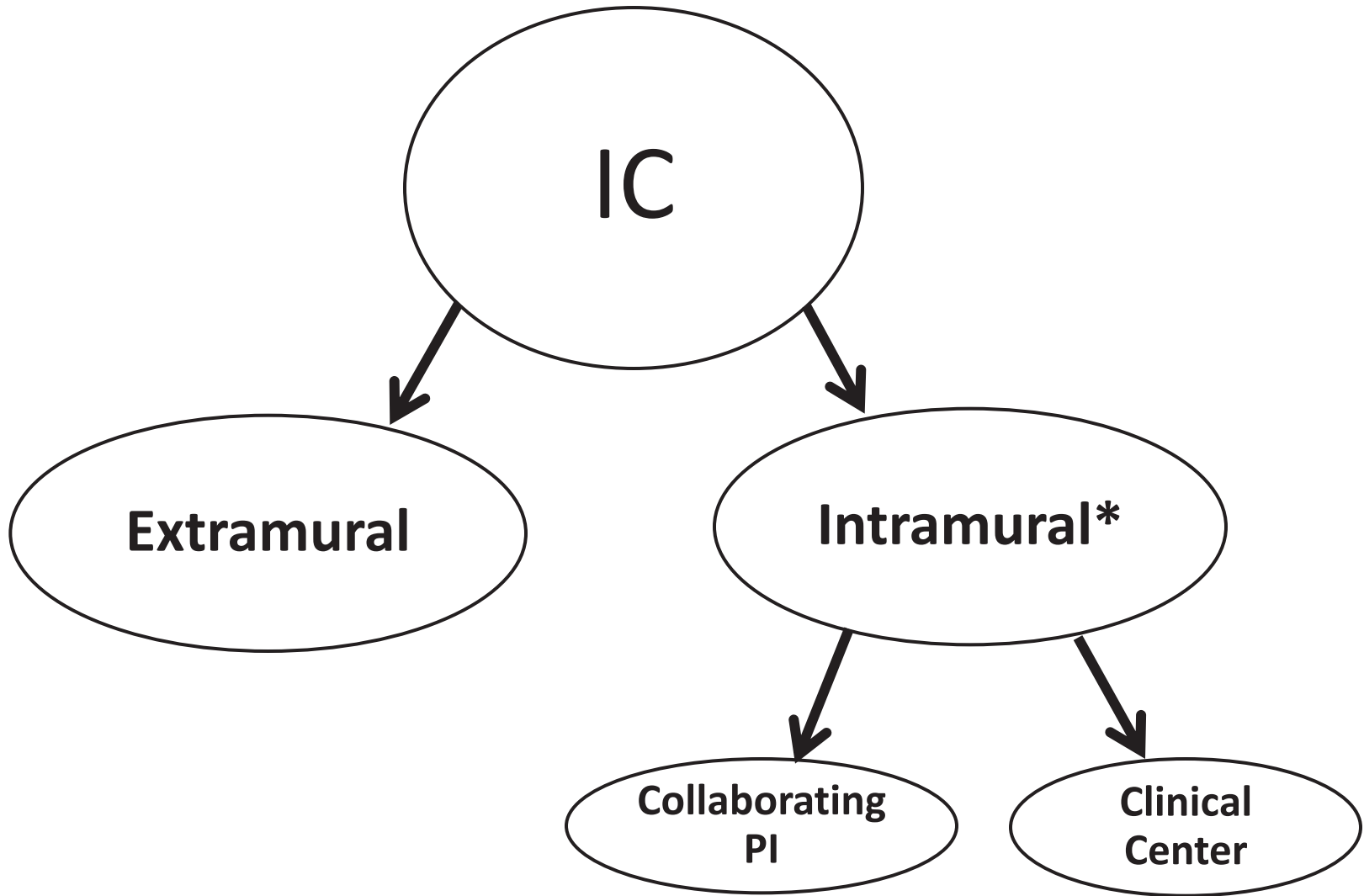
# **Intramural Clinical Center Budget Highlights**

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**Maria D. Joyce, CPA, MBA  
Chief Financial Officer,  
NIH Clinical Center**

# U01 Grant Money Flow

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**\*ICs have flexibility how these programs will be funded. Funds flow to be determined before award.**



# Preparing the Budget

## Extramural PI

- Detailed budget required; no modular budgets.
- Budget request for the intramural investigator and the Clinical Center should be listed separately in “Section F. Other Direct Costs”.

## Intramural PI

- The intramural PI will create a budget request limited to the proposed work.
- Budget may include contract staff, but not federal employees.

## Clinical Center

- Identify Clinical Center costs for grant as defined by the template provided.
- CC to work with ICs to define resource requirements for IC services (e.g., pulmonary function tests).
- Identify intramural PI before CC budget preparation begins.

# Sample Budget Template for CC Costs

Inpatient Services						
a) General Information:						
PI Name:*		Collaborating IC:*				
PI Institute:*		Collaborating PI:*				
Grant/Study name:*						
b) Cost per Inpatient Night:						
Year 1						
Projected # of Patients*	Projected # of inpatient days/patient*	Total # of IP Days	ICD-9 Code*	Cost/IP Day**	Estimated Cost**	
		0				
Year 2						
Projected # of Patients*	Projected # of inpatient days/patient*	Total # of IP Days	ICD-9 Code*	Cost/IP Day**	Estimated Cost**	
		0				
Year 3						
Projected # of Patients*	Projected # of inpatient days/patient*	Total # of IP Days	ICD-9 Code*	Cost/IP Day**	Estimated Cost**	
		0				
c) Technical Services Required for the Study:						
Year 1						
Test/Procedure/Service*	CPT code (if applicable)*	Projected # of Patients*	Projected # of services/patient*	Total # of Services	Cost/Service**	Estimated Cost**
				0		\$0
Year 1 SUBTOTAL						\$0
Year 2						
Test/Procedure/Service*	CPT code (if applicable)*	Projected # of Patients*	Projected # of services/patient*	Total # of Services	Cost/Service**	Estimated Cost**
				0		\$0
Year 2 SUBTOTAL						\$0
Year 3						
Test/Procedure/Service*	CPT code (if applicable)*	Projected # of Patients*	Projected # of services/patient*	Total # of Services	Cost/Service**	Estimated Cost**
				0		\$0
Year 3 SUBTOTAL						\$0

- Template includes easy-to-follow, step-by-step instructions for completion
- Separate tabs for:
  - Inpatient services
  - Outpatient services
  - Specialized research services

# Sample Budget Template for CC Costs (cont)

Year 1						
Drug Name*	HCPCS code (if applicable)*	Projected # of Patients*	Projected # of doses/patient*	Total # of Doses	Cost/Dose**	Estimated Cost**
				0		\$0
Year 1 SUBTOTAL						\$0
Year 2						
Drug Name*	HCPCS code (if applicable)*	Projected # of Patients*	Projected # of doses/patient*	Total # of Doses	Cost/Dose**	Estimated Cost**
				0		\$0
Year 2 SUBTOTAL						\$0
Year 3						
Drug Name*	HCPCS code (if applicable)*	Projected # of Patients*	Projected # of doses/patient*	Total # of Doses	Cost/Dose**	Estimated Cost**
				0		\$0
Year 3 SUBTOTAL						\$0
e) Specialized Research Services <sup>†</sup>						
Program				Check box if applicable		
Rehabilitation Medicine				<input type="checkbox"/>		
Human Motor Control Section				<input type="checkbox"/>		
Novel Cellular Biologics for Phase I/II Trials				<input type="checkbox"/>		
Pharmaceutical Development Service / GMP				<input type="checkbox"/>		
High-Throughput Molecular Assay				<input type="checkbox"/>		
Healthy Volunteer Program				<input type="checkbox"/>		
Production/Banking Bone Marrow Stromal Cells				<input type="checkbox"/>		
R&IS Bluemke - Cardiovascular Imaging- Non-Invasive Imaging of Coronary Artery Disease, Heart Failure and Atherosclerosis Imaging				<input type="checkbox"/>		
R&IS Frank - Stem Cell Images				<input type="checkbox"/>		
R&IS Neumann - Nuclear Medicine/Radiopharmaceutical Research				<input type="checkbox"/>		
R&IS Paik - Nuclear Medicine/Radiopharmaceutical Research				<input type="checkbox"/>		
R&IS Summers - Diagnostic Radiology				<input type="checkbox"/>		
R&IS Wood - Interventional Oncology				<input type="checkbox"/>		
*Specialized Research Services require completion of separate budget templates.						
Specialized Research Services Required by the Study:						
Year 1 Estimated Cost**						\$9,749
Year 2 Estimated Cost**						\$10,049
Year 3 Estimated Cost**						\$7,362
Total Costs per Year:						
Year 1 Total Costs (Inpatient, Technical Services, Drugs, Specialized Research Services)						\$9,749
Year 2 Total Costs (Inpatient, Technical Services, Drugs, Specialized Research Services)						\$10,049
Year 3 Total Costs (Inpatient, Technical Services, Drugs, Specialized Research Services)						\$7,362
TOTAL Estimated Cost for Study						\$27,160

- When complete, email to: [ClinicalCtrPartner@mail.nih.gov](mailto:ClinicalCtrPartner@mail.nih.gov).
- The Clinical Center Partner team will work with the investigator to provide accurate Clinical Center costs based on the completed template.
- Note: Applicants should allow sufficient time to identify and calculate these costs.

\*Input by Extramural Applicant

\*\*Input by Clinical Center

# Preparing the Budget

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**Urge early contact with Clinical Center staff for assistance**

**Clinical Center Partnerships Mailbox:**  
**[ClinicalCtrPartner@mail.nih.gov](mailto:ClinicalCtrPartner@mail.nih.gov)**

**Phone: 301.496.4121**

**Budget template submissions MUST be made prior to March 1, 2013 to meet project deadlines**

# Thank You

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- Please email any questions to:  
[ClinicalCtrPartner@mail.nih.gov](mailto:ClinicalCtrPartner@mail.nih.gov)
- Questions received today will be addressed during the panel discussion at the end of this webinar

# **Tips for Preparing the Application**

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**Anna L. Ramsey-Ewing, Ph.D.**

**Director, Office of Extramural Research Policy  
and Operations**

**NIAID**

# Overview

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- **General Grantsmanship Tips**
- **Funding Opportunity Announcement (FOA) Structure**
  - **Application and Submission Information**
- **FOA-Specific Requirements and Considerations**
  - **Application Structure**
  - **Applications that Include Clinical Trials**
  - **Selection Criteria**
- **Electronic Submission Tips**
  - **Electronic Submission-General Reminders**
  - **FOA-Specific E-Submission Issues**
- **Resources**

# General Grantsmanship Reminders

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- Identify and utilize your partners
  - Assemble a team of reviewers (SME, non-SME)
  - Your institutional officials
  - NIH staff
- Use extensive internet resources
  - Review funded clinical trial abstracts and public health relevance statements in NIH RePORTER
  - Review examples of funded applications
  - Review tutorials
- ***Read the entire FOA!***



# General FOA Structure

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- **Overview**
  - Key Dates
- **Full Text**
  - Description
  - Award, Eligibility Information
  - *Application and Submission Instructions*
  - Application Review Information
  - Award Administration
  - Agency Contacts, Other Information

# Application Structure Matters

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- Components of the application are aligned with the review criteria
- Required application inclusions reflect information NIH deems necessary for high quality peer review
- All FOA-specific instructions must be followed
- Peer reviewers are required to evaluate the entire application; they may consider the appendix

# IV. Application and Submission Information

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## FOA-specific requirements

- Collaboration Plan [Approach]
- Letters of Support (also collaboration approvals) [Approach]
- MPI Leadership Plan (include the DIR PI) [Investigator(s)]
- Resource Sharing Plan [review consideration]

***Applications that lack any of these items will not be reviewed!***

# IV. Application and Submission Information

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## FOA-specific requirements:

- Budget [review consideration]
  - Budget **must** delineate extramural, intramural and Clinical Center costs
  - CC costs calculated using template from CC CFO
  - Intramural costs determined by discussion with intramural partner
  - Append spreadsheets as per FOA instructions
  - Non-modular only

# Applications that Include Clinical Trials

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- Must fully address human subjects protections issues; evaluated as a review consideration and under “Approach” scored criterion
- Require special components at the time of application submission
  - In the application
    - Clinical Protocol Synopsis
    - Statistical Analysis Plan
    - Data and Safety Monitoring Plan
    - Milestone Plan and Complete Protocol

# Applications that Include Clinical Trials

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## -In the appendix

- The informed consent form(s) and, if applicable, assent form(s)
- Identification and qualifications of clinical trial site(s), pharmacies and laboratories
- Copies of data collection forms, questionnaires or other relevant materials
- The Investigator's Brochure or equivalent for the study products(s)
- The Table of Contents of the Manual of Procedures
- A comprehensive Laboratory Plan
- Documentation of availability of and support for acquisition/administration of study agent(s)
- A statement addressing the need (if applicable) for IND approval from the FDA
- The Data Management Plan
- The Site Quality Management Plan

# Funding Decision Considerations

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- Scientific and technical merit of the proposed project as determined by scientific peer review.
  - Availability of funds.
  - Relevance of the proposed project to program priorities.
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## FOA-Specific

- Compliance with resource sharing policies.
- Likelihood of effective collaboration between the PD(s)/PI(s) of the applicant institution and the NIH Intramural Investigator.
- Utilization of unique research opportunities in the Clinical Center.

# **General E-Submission Tips**

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- **Update eRA Commons information**
- **Assign delegate, if appropriate**
- **Identify institutional resources**
- **Utilize different types of reviewers**
- **PDF guidance**
- **Warnings vs. Errors**
- **View your application**



# FOA-Specific E-Submission Issues

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- Multiple PI requires the intramural investigator to register in the eRA Commons
- Optional Components that are required include:

**All EXCEPT modular budget!**

- SF424 (R&R) Other Project Information
  - Item 12 Other attachments
  - Filenames are important

[Save & Submit](#)[Save](#)[Print](#)[Cancel](#)[Check Package for Errors](#)

GRANTS.GOV™

## Grant Application Package

Opportunity Title:	Research Project Grant (Parent R01)
Offering Agency:	National Institutes of Health
CFDA Number:	
CFDA Description:	
Opportunity Number:	PA-10-067
Competition ID:	ADOBE-FORMS-B
Opportunity Open Date:	01/05/2010
Opportunity Close Date:	01/07/2013
Agency Contact:	Grants Info Grants Information E-mail: GrantsInfo@nih.gov Phone: 301-435-0714

This electronic grants application is intended to be used to apply for the specific Federal funding opportunity referenced here.

If the Federal funding opportunity listed is not the opportunity for which you want to apply, close this application package by clicking on the "Cancel" button at the top of this screen. You will then need to locate the correct Federal funding opportunity, download its application and then apply.

**Prefilled Header Information**

This opportunity is only open to organizations, applicants who are submitting grant applications on behalf of a company, state, local or tribal government, academia, or other type of organization.

\* Application Filing Name:

### Mandatory Documents

Sr424 (R & R)  
Project/Performance Site Location(s)  
Research And Related Other Project Information  
Research And Related Senior/Key Person Profile  
PHS 398 Cover Page Supplement  
PHS 398 Research Plan  
PHS 398 Checklist

Move Form to Complete



Move Form to Delete



### Mandatory Documents for Submission

[Open Form](#)

### Optional Documents

~~PHS Cover Letter~~  
PHS 398 Modular Budget  
Research & Related Budget  
R & R Subaward Budget Attachment(s) Form

Move Form to Submission List



Move Form to Delete

### Optional Documents for Submission

**Select all except modular budget**

# PHS 398 Research Plan

## 1. Application Type:

From SF 424 (R&R) Cover Page. The response provided on that page, regarding the type of application being submitted, is repeated for your reference, as you attach the appropriate sections of the Research Plan.

\*Type of Application:

☐ New ☐ Resubmission ☐ Renewal ☐ Continuation ☐ Revision

## 2. Research Plan Attachments:

Please attach applicable sections of the research plan, below.

- |   |                      |   |  |  |
|---|----------------------|---|--|--|
| 1. Introduction to Application<br>(for RESUBMISSION or REVISION only) | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 2. Specific Aims  | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 3. *Research Strategy   | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 4. Inclusion Enrollment Report  | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 5. Progress Report Publication List                                   | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |

### Human Subjects Sections

- |                                      |                      |   |  |  |
|--------------------------------------|----------------------|---|--|--|
| 6. Protection of Human Subjects      | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 7. Inclusion of Women and Minorities | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 8. Targeted/Planned Enrollment Table | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 9. Inclusion of Children             | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |

### Other Research Plan Sections

- |   |                      |   |  |  |
|---|----------------------|---|--|--|
| 10. Vertebrate Animals                  | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 11. Select Agent Research               | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 12. Multiple PD/PI Leadership Plan      | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 13. Consortium/Contractual Arrangements | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 14. Letters of Support                  | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |
| 15. Resource Sharing Plan(s)            | <input type="text"/> | <input type="button" value="Add Attachment"/> | <input type="button" value="Delete Attachment"/> | <input type="button" value="View Attachment"/> |

16. Appendix

# PHS 398 Research Plan

## 2. Research Plan Attachments:

Please attach applicable sections of the research plan, below.

1. Introduction to Application

(for RESUBMISSION or REVISION only)

Add Attachment

2. Specific Aims

Add Attachment

3. \*Research Strategy

Add Attachment

4. Inclusion Enrollment Report

Add Attachment

5. Progress Report Publication List

Add Attachment

# PHS 398 Research Plan

## Other Research Plan Sections

10. Vertebrate Animals

Add Attachment

11. Select Agent Research

Add Attachment

12. Multiple PD/PI Leadership Plan

Add Attachment

13. Consortium/Contractual Arrangements

Add Attachment

14. Letters of Support

Add Attachment

15. Resource Sharing Plan(s)

Add Attachment

# Other Project Information

## Item 12: Other Attachments

1. \* Are Human Subjects Involved?

☐ Yes ☐ No

1.a If YES to Human Subjects

Is the Project Exempt from Federal regulations? ☐ Yes ☐ No

If yes, check appropriate exemption number. ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

If no, is the IRB review Pending? ☐ Yes ☐ No

IRB Approval Date:

Human Subject Assurance Number:

2. \* Are Vertebrate Animals Used?

☐ Yes ☐ No

2.a If YES to Vertebrate Animals

Is the IACUC review Pending? ☐ Yes ☐ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. \* Is proprietary/privileged information included in the application?

☐ Yes ☐ No

4.a. \* Does this project have an actual or potential impact on the environment?

☐ Yes ☐ No

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed?

☐ Yes ☐ No

4.d. If yes, please explain:

5. \* Is the research performance site designated, or eligible to be designated, as a historic place?

☐ Yes ☐ No

5.a. If yes, please explain:

6. \* Does this project involve activities outside of the United States or partnerships with international collaborators?

☐ Yes ☐ No

6.a. If yes, identify countries:

6.b. Optional Explanation:

7. \* Project Summary/Abstract

Add Attachment

Delete Attachment

View Attachment

8. \* Project Narrative

Add Attachment

Delete Attachment

View Attachment

9. Bibliography & References Cited

Add Attachment

Delete Attachment

View Attachment

10. Facilities & Other Resources

Add Attachment

Delete Attachment

View Attachment

11. Equipment

Add Attachment

Delete Attachment

View Attachment

12. Other Attachments

Add Attachments

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View Attachments

☐

FOA-specific additional components

# Budget Justifications

## H. Indirect Costs

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	* Funds Requested (\$)
1.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
2.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
3.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
4.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Total Indirect Costs				<input type="text"/>

**No F & A for  
intramural**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

## I. Total Direct and Indirect Costs

Total Direct and Indirect Institutional Costs (G + H)

Funds Requested (\$)

## J. Fee

Funds Requested (\$)

K. \* Budget Justification

(Only attach one file.)

Add Attachment

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View Attachment

# Grantsmanship Resources (NLM)

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## Grant-writing tip sheets for NIH research grants

- All About Grants - A multi-part site, including sections on Grant Application Basics, How to Plan a Grant Application, How to Write a Grant Application. These documents are in PDF form (NIAID)  
<http://www.niaid.nih.gov/researchfunding/qa/pages/applygenplan.aspx>
- Quick Guide for Research Grant Applications (NCI)  
<http://deainfo.nci.nih.gov/extra/extdocs/gntapp.htm>
- Tips for New NIH Grant Applicants (NIGMS)  
<http://www.nigms.nih.gov/Research/Application/Tips.htm>
- Common mistakes in grant applications (NINDS)  
[http://www.ninds.nih.gov/funding/grantwriting\\_mistakes.htm](http://www.ninds.nih.gov/funding/grantwriting_mistakes.htm)
- Writing a grant application: A Technical Checklist  
[http://www.ninds.nih.gov/funding/grantsmanship\\_checklist.htm](http://www.ninds.nih.gov/funding/grantsmanship_checklist.htm)
- Annotated Sample R01 grant (from NIAID)  
<http://www.niaid.nih.gov/ncn/grants/app/default.htm>



# E-Submission Resources (NLM)

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## Electronic Submission of Grant Applications

- NIH began accepting electronic applications in 2005. Basic explanation of all aspects of the Electronic submission (text and links)  
<http://era.nih.gov/ElectronicReceipt/>
- SF424, the new electronic application form that is replacing PHS 398 (slideshows and videocasts)  
<http://era.nih.gov/ElectronicReceipt/sf424.htm>
- All electronic applications require advance registration at both Grants.gov and the NIH eRA Commons. (explanation and links to both registration sites)  
<http://era.nih.gov/ElectronicReceipt/preparing.htm>

# Thank You

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- Please email any questions to:  
[ClinicalCtrPartner@mail.nih.gov](mailto:ClinicalCtrPartner@mail.nih.gov)
- We will now address any questions.
- Video archive of today's session and the Q+A's will be posted on the Clinical Center website.